

Applicants: James Binley et al.

Serial No.: 10/780,993

Filed: January 18, 2004

**Exhibit 2**

# Office Action Summary

Application No.

10/780,993

Applicant(s)

BINLEY, J. M., ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Serial No.: 10/780,993  
Applicants: Binley, J. M., et al.

Docket No.: N/A  
Filing Date: 02/18/2004

### Restriction Requirement

#### 35 U.S.C. § 121

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 87-96, 111-113, 126-135, and 150-152, drawn to a **DNA** encoding a modified HIV-1 envelope glycoprotein, classified in class 536, subclass 23.72.
- b. Group II, claim(s) 97-104 and 136-143, drawn to a non-replicating viral **vector**, classified in class 435, subclass 320.1.
- c. Group III, claim(s) 105-110 and 144-149, drawn to a **host cell**, classified in class 435, subclass 325.
- d. Group IV, claim(s) 114, 116, 153, and 155, drawn to a modified **gp120-gp41 complex**, classified in class 424, subclass 188.1.
- e. Group V, claim(s) 115 and 154, drawn to a **method of making** a modified gp120-gp41 complex, classified in class 435, subclass 70.1.
- f. Group VI, claim(s) 117-119, 122-124, 156-158 and 161-163, drawn to a **DNA vaccine**, classified in class 514, subclass 44.
- g. Group VII, claim(s) 120, 121, 159, and 160, drawn to a **proteinaceous vaccine**, classified in class 424, subclass 208.1.
- h. Group VIII, claim(s) 122-124 and 161-163, drawn to a **vaccine** comprising a **nonreplicating viral vector**, classified in class 424, subclass 204.1.
- i. Group IX, claim(s) 125 and 164, drawn to a **vaccine** comprising both **DNA** and **protein**, classified in class 514, subclass 44, and class 424, subclass 208.1.

The inventions are distinct, each from the other because of the following reasons:

#### *Unrelated Inventions*

Inventions I-IV and VI-IX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a structurally/functionally different product/composition (e.g., DNA, vectors, cell lines, complexes, various vaccine compositions) with different uses. Separate searches will clearly be required for each group. Therefore, each group is clearly drawn toward a different inventive entity.

#### *Product and Process of Making*

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the complex can be prepared by a materially different method such as affinity purification of each of the individual components followed by complex formation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is also advised that the claims should be amended to reflect the election, where necessary..

**37 C.F.R. § 1.48(b)**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

**Claim Rejoinder (M.P.E.P. § 821.04)**

Applicants are reminded that a restriction between product and process claims has been set forth supra. When applicant elects claims directed to the product, and a product claim is subsequently found to be allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of § 821.04 of the M.P.E.P. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116 while amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for

patentability as set forth under 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so will result in a loss of the right to rejoinder.** Furthermore, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

#### **Correspondence**

The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

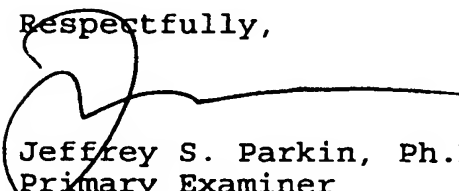
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered

to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Primary Examiner  
Art Unit 1648

30 September, 2006



# UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office  
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10/780,993	02/18/2004	James M. Binley	59331-E/JPW/AJD/BWSL	9456

7590

10/05/2006

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.